UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	[illegible]	D [illegible]

18N2/0313

GREGORY D FERRARO
CARELLA BYRNE BAIN GILFILLAN CECCHI
STEWART & OLSTEIN
6 BECKER FARM ROAD
ROSELAND NJ 07068

EXAMINER	
ART UNIT	**PAPER NUMBER**
1812	9

DATE MAILED: 03/13/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 1/2/97 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☒ Seq. Compliance.

Part II SUMMARY OF ACTION

1. ☒ Claims 21-41 are pending in the application.
   Of the above, claims ______ are withdrawn from consideration.
2. ☒ Claims 1-20 have been cancelled.
3. ☐ Claims ______ are allowed.
4. ☒ Claims 21-41 are rejected.
5. ☐ Claims ______ are objected to.
6. ☐ Claims ______ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed ______, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ______ ; filed on ______.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. Claims 21-41 are pending in the instant application.

Applicant's election of Group I, claims 1-7, in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21-41 are examined in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is not clear what HLTDG74 is.

Reference AR has not been considered because it is not a publication.

3. The specification is objected to as not complying with §1.821(d) of the Sequence Rules and Regulations. When the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulation, reference must be made to the sequence by use of the assigned identifier, in the text of the description and claims of the patent application. Further, § 2422.02 of the MPEP states, "...when a sequence is presented in a drawing,...the sequence identifier (SEQ ID NO: X) must be used either in the drawing or in the Brief Description of Drawings." Figure 3 discloses sequences that are not set forth in the Sequence Listing. Applicant is required to submit a new Sequence Listing containing all the sequences disclosed in the specification, including those in the figures, a new CRF, an amendment directing the entry of the new Sequence Listing into the specification, and a statement regarding the content of the CRF and Sequence Listing (see

attached Sequence Compliance Notice).

Also, it is pointed out that 37 CFR § 1.822(e) requires the exclusive use of three-letter abbreviations to depict amino acids in an amino acid sequence (MPEP § 2423). Figure 3 discloses amino acid sequences using one-letter abbreviations. Correction is required.

4. The amendments filed September 7, 1996, and January 2, 1997, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: page 12 line 12, page 34 line 32, page 37, line 3, page 38, line 5, and page 7 line 12. The specification as originally filed does not provide support for a cDNA clone having ATCC Deposit No. 97186. There is no evidence that the deposited nucleic acid encodes the parathyroid hormone receptor isolated by applicant. It is not clear what sequence the deposited clone has or what protein it encodes. Applicant is required to cancel the new matter in the response to this Office action.

In order to have the ATCC Deposit No. entered, applicant must provide evidence that the parathyroid hormone receptor disclosed in the specification is encoded by the nucleic acid having ATCC Deposit No. 97186.

Applicant is required to cancel the new matter in the response to this Office action.

5. Claims 37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 37 and 39 are directed to a polynucleotide that is identical to the cDNA having ATCC Deposit No. 97186. As discussed above, the specification as originally filed does not provide support for a cDNA having ATCC Deposit No. 97186. Although the nucleic acid encoding the isolated parathyroid hormone is encoded by SEQ ID NO: 1, there is no evidence that the cDNA having ATCC Deposit No. 97186 is SEQ ID NO: 1.

6. Claims 21-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

SAT The claims are directed to a nucleic acid encoding a polypeptide having SEQ ID NO: 2. However, the specification does not adequately teach how to use the claimed nucleic acid. It is acknowledged that the encoding polypeptide is a G-protein coupled receptor, but the specification does not teach what ligands the receptor binds and what activities the polypeptide mediates. In the absence of such guidance, it would require undue experimentation of the skilled artisan to use the disclosed polypeptide as a G-protein coupled receptor. G-protein coupled receptor family consists of diverse members having distinct functional properties. Examples of a few members of the family include the receptors for prostaglandin, secretin, calcitonin, gastrin releasing peptide, opioid, and endothelin. Although these receptors are structurally related-- they all have seven

transmembrane domains, they do not interact with the same ligands and do not mediate the same cellular processes. Accordingly, one cannot predict the ligands that the polypeptide disclosed by the present specification interacts with. Thus, knowing that a protein has seven transmembrane domains does not enable the skilled artisan to use the protein as a G-protein coupled receptor. It is also acknowledged that the disclosed protein has 48% sequence identity with the parathyroid hormone receptor. However, in the absence of evidence that the polypeptide interacts with parathyroid hormone, one would not expect the disclosed protein to bind to parathyroid hormone. The functional properties of a protein is determined by its primary sequence. A single amino acid change can alter the activity of a protein completely. Therefore, it is not predictable that a protein having only 48% sequence identity with the parathyroid hormone receptor has the same functional properties as the parathyroid hormone receptor.

Since the specification only teaches the use of the nucleic acid to make the protein and since the specification has not enabled the skilled artisan to use the protein, the specification does not enable the skilled artisan to use the nucleic acid.

Claims 31-33 and 41 are not enabled by the specification because they are incomplete as method claims. The preamble of the claims recites a method of producing a polypeptide but the recited steps are directed to expression of a recombinant cell. The claims are missing steps such as culturing the host cell under conditions that allow expression of the polypeptide and isolating the polypeptide from the host cell. Additionally, the specification does not enable cells that endogenously express the polypeptide. The specification only enables host cells transfected with the nucleic acid encoding the polypeptide.

7. Claims 21, 22, 23, 30-33, 37, 38, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 21 and 37, it is not clear what is encompassed by the term "95% identity". Is the term referring to sequence identity? The specification does not define "95% identity". It is not clear whether the percentage is obtained by comparing two sequences having the same length or different length. Are the sequences aligned to maximize sequence identity?

The phrase "wherein said member is (a)" renders claims 22 and 38 vague and indefinite. It is not clear whether the isolated polynucleotide is member (a) or the isolated polynucleotide has at least 95% identity with member (a).

Claim 23 is confusing because it is not clear whether the isolated polynucleotide is member (a) or has 95% identity with member (a). Additionally, if said member is (a) then the polypeptide cannot comprise amino acids 1 to 349 of SEQ ID NO: 2. Member (a) is a polynucleotide encoding a polypeptide comprising amino acids 2 to 349 of SEQ ID NO: 2.

In claim 30, it is not clear whether the host cell is transfected with the polynucleotide of claim 22 or endogenously expresses the polynucleotide of claim 22. It is suggested that the claim be amended in the following approximate manner, "A host cell transfected with the polynucleotide of claim 22...."

Claims 31-33 and 41 are vague and indefinite because the preamble is not consistent with the recited steps and it is not exactly clear as to what the recombinant cell contains. The preamble of each claim is directed to a method of producing a polypeptide but the recited steps are directed

to expressing a recombinant cell. The claims seem to be missing steps for culturing the host cell transformed with the polynucleotide under conditions that allow expression of the polypeptide and for isolating the polypeptide. It is also not clear whether the cell is transformed with the polynucleotide or contains the polynucleotide endogenously. Additionally, it is suggested that the claims be amended by replacing the term "recombinant cell" with "host cell". (Claim 30 would also have to be amended accordingly.)

8. It is suggested that claims 24, 26, and 34-36 be amended in the following approximate manner to clarify the claimed invention, "The isolated polynucleotide of claim 21, wherein said polynucleotide encodes (comprises)...."

9. The claims are free of the prior art.

Any inquiry concerning this communication should be directed to Sally Teng, Ph.D., at telephone number (703)308-4230. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Walsh, can be reached at telephone number (703)308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703)308-0294.

March 12, 1997

SALLY TENG
PATENT EXAMINER
GROUP 1800

Application No.: 08/468,011

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

[X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

[ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

[ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

[ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

[ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

[X] 7. Other: Figure 3 discloses sequences that are not set forth in the Sequence Listing.

Applicant Must Provide:

[X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

[X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE